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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/900,647	07/07/2001	Dale R. Lovercheck	ANAL-VIT	6584

7590 07/02/2002

Dale R. Lovercheck, Esquire
92 Patricia Place
Media, PA 19063

EXAMINER

HUI, SAN MING R

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 07/02/2002

6

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/900,647

Applicant(s)

LOVERCHECK, DALE R.

Examiner

San-ming Hui

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 May 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 26-45 is/are pending in the application.
- 4a) Of the above claim(s) 31 and 36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 26-30, 32-35 and 37-45 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

The cancellation of claims 1-15 and 21-25 in amendments filed May 15, 2002 is acknowledged.

Applicant's election of claims 26-45 (corresponding to the original invention of Group II) in Paper No. 5, received May 15, 2002 is acknowledged. In addition, Applicant's election of the nutritional supplement specie as vitamin C and the discomfort reliever as ibuprofen is also acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 26-45 are pending.

Claims 31 and 36 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 5, received May 15, 2002.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 26-30, 32-35, and 37-45 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "providing" in the claims renders the claims (e.g., claims 26, 29, 30, 35, 38, 44) indefinite as to the active method step herein. It is not clear how the providing

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step encompasses. It is apparent the method herein encompasses the step of enclosing the orally consumable material in an enclosure. If it is so, the examiner would favorably considered phrases such as "enclosing" or "placing the orally...material into an enclosure".

Regarding claims 34 and 42, the phrase "or the like" renders the claim(s) indefinite because the claim(s) include(s) elements not actually disclosed (those encompassed by "or the like"), thereby rendering the scope of the claim(s) unascertainable. See MPEP § 2173.05(d).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 26-30, 32-35, and 37-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over SS Pharmaceutical (Comline Biotechnology & Medical, 1 Dec. 1992, page 4) in view of Tsunoda (JP 2000-229853, English abstract is also provided), Yeh et al. (US Patent 5,032,384), and Lambelet (US Patent 5,833,072).

SS Pharmaceutical teaches a composition containing ibuprofen and a high content of vitamin C (See the abstract).

SS Pharmaceutical does not expressly teach the amount of ibuprofen and vitamin C as at least 50mg. SS Pharmaceutical does not expressly teach the

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composition is in an enclosure. SS Pharmaceutical does not expressly teach the composition is in an unit form as pill, tablet, or capsule. SS Pharmaceutical does not expressly teach the composition is package with an indicator indicating the amount of each ingredients and the indication.

Tsunoda teaches a pain-alleviating tablet containing 300-500mg of ibuprofen and about 30-50mg of vitamin C (See the abstract).

Yeh et al. teaches a composition containing an antioxidant, such as ascorbic acid, and a NSAID, such as ibuprofen, such that the weight amount of the antioxidant and the NSAID is about 0.01 to 10% of the composition (See particularly the abstract, also col. 4, line 7-10). Yeh et al. also teaches that the composition can be formulated into oral dosage forms (See particularly col. 3, line 67).

Lambelet teaches a dosage regimen container with indicator, such as memory aid, for the drug delivery (See the abstract and col. 1, line 60 - col. 2, line 1; also claims 1-6).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ the amount of ibuprofen and vitamin C in the amount herein claimed into the composition claimed herein. It would have been obvious to one of ordinary skill in the art at the time the invention was made to formulate the ibuprofen-vitamin C composition into tablet unit dose and enclose the same into a container with indicator indicating the amount of each ingredients and the indication.

One of ordinary skill in the art would have been motivated to employ the amount of ibuprofen and vitamin C in the amount herein claimed into the instant composition

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herein because the optimization of result effect parameters (e.g., dosage range) is obvious as being within the skill of the artisan.

One of ordinary skill in the art would have been motivated to formulate the ibuprofen-vitamin C composition into tablet unit dose and enclose the same into a container with indicator because interconversion of dosage forms, such as from a multiple dosage form to unit dosage forms, would be obvious as being within the skill of the artisan. Possessing the teachings of the cited prior art, the skilled artisan would reasonably expect enclosing the unit dosage in a package or container with the indicator indicating the amount of each ingredients and the indication to be useful in formulating the ibuprofen-vitamin C composition. Furthermore, inclusion of a package insert or label showing the "indication and direction of use" of a pharmaceutical composition is mandated by 21 CFR 201.57 and is therefore obvious to one of ordinary skill in the art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (703) 305-1002. The examiner can normally be reached on Mon 9:00 to 1:00, Tu - Fri from 9:00 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

San-ming Hui
July 1, 2002

RUSSELL TRAVERS
PRIMARY EXAMINER
GROUP 1200